PATENT
Atty. Docket No.: Le A 35 012

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: Henning, *et al.*

SERIAL NO.: New filing

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TITLE: Method for Increasing Clinical Specificity when Detecting Tumours and Their Precursor Stages by Simultaneously Measuring At Least Two Different Molecular Markers

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PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

This Preliminary Amendment is submitted in the above-captioned application. Please amend the application as follows:

In the Claims

Please amend claims 1-7, as shown in the attached sheets. A marked version of the claim set showing the changes made is also attached.

Remarks

By way of this Preliminary Amendment, claims 1-7 are pending. Claims 1-7 have been amended. These claim amendments are being made solely for purposes of placing the claims in a format appropriate for U.S. prosecution. No new matter was added by way of these claim amendments and additions.

More specifically, claims 2-7 are being amended to remove the improper multiple dependent claim format in compliance with 37 C.F.R. § 1.75(c). Applicants submit that all of these amendments do not change the scope of the claims as originally filed, because the amendments are being made solely to place the claims in a format appropriate for U.S. prosecution. Such amendments are therefore made to address formalities in the claim format and are not related to the patentability of the subject matter of the claims.

Conclusion

Applicants believe that the subject matter of the pending claims is patentable and that the instant application should accordingly be allowed. If the Examiner believes that a conversation with Applicants' attorney would be helpful in expediting prosecution of this application, the Examiner is invited to call the undersigned attorney at (203) 812-6450.

Respectfully submitted,

Dated: December 17, 2001

Susan M. Pellegrino
Attorney for Applicants
Reg. No. 48,972

Bayer Corporation
400 Morgan Lane
West Haven, CT 06516
(Tel) (203) 812-6450
(Fax) (203) 812-6459
e-mail: susan.pellegrino.b@bayer.com

Amended Claims (Attorney Docket No. Le A 35 012)

1. (Amended) An automatable method for identifying cancer cells and their precursors, characterized in that at least two markers in a cell or a tissue sample are detected simultaneously and the signal intensities are combined and accredited.

2. (Amended) The method according to claim 1, further characterized in that the automatic information processing is linked to a diagnostic expert system which consolidates the image information into a proposed diagnosis.

3. (Amended) The method according to claim 1, wherein the molecular markers are detected quantitatively by analysing chromogenic colour reactions or fluorescence signals in constituent regions of the tissue sample, with secondary colours or the spatial proximity of the individual colours when using at least two markers providing additional information as compared with single stainings.

4. (Amended) The method according to claim 1, wherein marker combinations are selected from the group consisting of:
her2/neu and Ki67, her2/neu and p53, her2/neu and bcl-2, her2/neu and MN, her2/neu and mdm-2, her2/neu and EGF receptor, bcl-2 and Ki67, bcl-2 and MN, bcl-2 and mdm-2, bcl-2 and EGF receptor, her2/neu and bcl-2, p53 and bcl-2, p53 and MN, p53 and mdm-2, p53 and EGF receptor, p16 and p53, p16 and MN, p16 and mdm-2, p16 and EGF receptor, p16 and Ki67, p16 and her2/neu, p16 and bcl-2, MN and mdm-2, MN and EGF receptor, mdm-2 and EGF receptor.

5. (Amended) The method according to claim 1, further characterized in that tumours of the mammary gland, the lung, the cervix, the colon, the skin and the prostate are detected.

6. (Amended) The method according to claim 1, characterized in that it involves reflex testing.

7. (Amended) A test kit for implementing the method according to claim 1 containing all the necessary reagents.

Amended Claims (Attorney Docket No. Le A 35 012)
Version with Markings to Show Changes to Claims

1. (Amended) An automatable method for identifying cancer cells and their precursors, characterized in that at least two markers in a cell or a tissue sample are detected simultaneously and the signal intensities are combined and accredited.

2. (Amended) The method according to claim 1, further characterized in that the automatic information processing is linked to a diagnostic expert system which consolidates the image information into a proposed diagnosis.

3. (Amended) The method according to claim[s] 1 [to 2], wherein [characterized in that] the molecular markers are detected quantitatively by analysing chromogenic colour reactions or fluorescence signals in constituent regions of the tissue sample, with secondary colours or the spatial proximity of the individual colours when using at least two markers providing additional information as compared with single stainings.

4. (Amended) The method according to claim[s] 1 [to 3], wherein [characterized in that the following] marker combinations are selected from the group consisting of [detected]:
her2/neu and Ki67, her2/neu and p53, her2/neu and bcl-2, her2/neu and MN, her2/neu and mdm-2, her2/neu and EGF receptor, bcl-2 and Ki67, bcl-2 and MN, bcl-2 and mdm-2, bcl-2 and EGF receptor, her2/neu and bcl-2, p53 and bcl-2, p53 and MN, p53 and mdm-2, p53 and EGF receptor, p16 and p53, p16 and MN, p16 and mdm-2, p16 and EGF receptor, p16 and Ki67, p16 and her2/neu, p16 and bcl-2, MN and mdm-2, MN and EGF receptor, mdm-2 and EGF receptor.

5. (Amended) The method according to claim[s] 1 [to 4], further characterized in that tumours of the mammary gland, the lung, the cervix, the colon, the skin and the prostate are detected.

6. (Amended) The method according to claim[s] 1 [to 5], characterized in that it involves reflex testing.

7. (Amended) A test kit for implementing the method according to claim[s] 1 [to 6] containing all the necessary reagents.